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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,782	07/13/2001	Suresh K. Tikoo	293102002900	1838
25226	7590	03/21/2006	EXAMINER	
MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018			HILL, MYRON G	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 03/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/904,782

Applicant(s)

TIKOO, SURESH K.

Examiner

Myron G. Hill

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,5-15,18-21 and 29-44 is/are pending in the application.
- 4a) Of the above claim(s) 9,12,13,22-28 and 31-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5-8,10,11,14,15,18-21,29,30 and 39-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/28/05.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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***DETAILED ACTION***

The finality of the previous action is withdrawn as was indicated in the interview of September 7, 2005 with James Housel.

The Group and/or Art Unit of your application has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648, Examiner Hill.

This action is in response to the papers filed September 28, 2005.

Claims 1, 5-8, 10, 11, 14, 15, 18-21, 29, 30, and 39-44 are under consideration.

***Rejections Necessitated By Amendment***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 44 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled

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in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "parallel orientation" in claim 44 is used by the claim to mean "expressed", while the accepted meaning does not make any sense in this context. The term is indefinite because the specification does not clearly redefine the term. Paragraph 123 indicates that the term is used to indicate that transgene is expressed. This is not a limiting definition of the term in the specification and from common use it does not indicate that the transgene is expressed. It is interpreted as expressed in this Office Action.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 5-8, 10, 11, 14, 15, 18-21 29, 30, and 39-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lusky *et al.* (which is in French and US 6479290 is used as noted by applicant in the response) in view of Matthews *et al.* and further in view of Kaufman *et al.* The intron of Kaufman *et al.* is cited and used in Matthews *et al.* and the reference is provided to show features not explicitly taught in Matthews *et al.*

Applicant argues that there is no motivation to combine the references, Lusky *et al.* fail to teach the intron or replication competent bovine adenovirus, that Matthews *et al.* does not suggest splicing or replication competent vectors or insertion in the E3

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region, applicant asserts that the art teaches limitations of BAV3 E3, and finally that Matthews *et al.* teaches attempts to make certain constructs failed.

Applicants arguments have been fully considered and not found persuasive.

Lusky *et al.* do teach BAV3 vectors (Figures 15 A and 15B, column 12, and Example 4). The motivation to combine them comes from common knowledge in the art and knowing that the vectors of Lusky *et al.* are for heterologous gene expression and Matthews *et al.* teach a cassette for expression in Adenovirus that increases the level of expression of the gene of interest. One of ordinary skill in the art at the time of invention would have desired higher expression for at least reasons noted by Matthews *et al.* which states that the level of protection correlated with antigen expression cell culture and that the transgene is inserted in the E3 region (page 345, column 1 first paragraph). This same paragraph also indicates that both infectious and defective adenovirus vectors are known. One of ordinary skill in the art at the time of invention would have known the BAV3 E3 region and that the E3 is not required for adenovirus replication.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Matthews *et al.* does teach splicing and hybrid introns (page 346, column 1, last full paragraph) and replication competent vectors (page 345 first paragraph). The hybrid intron used by Matthews *et al.* is taught by Kaufman *et al.* (abstract). This also meets

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the limitations for splice junction sequence and hybrid intron as well as strong donor/acceptor as defined in the specification (paragraphs 65-66). Other introns including mammalian are known in the art.

Matthews *et al.* does teach that certain constructs made with this gene did fail. The intron expression cassette and helper cells allowed for the control of expression and enabled a recombinant vector to be made that expresses the gene of interest.

The use of heterologous promoters is known and present in both of the cited references, see Matthews *et al.* page 346, paragraph spanning column 1 and 2 for CMV promoter which is heterologous to the adenovirus and the transgene.

It would be obvious to one of ordinary skill in the art to insert the expression cassette in a manner that the cassette is expressed (parallel orientation as recited).

Thus, the claims are unpatentable over the cited art.

### **Conclusion**

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

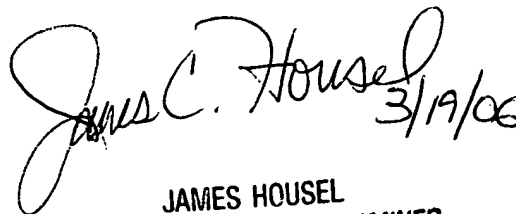
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Myron G. Hill  
Patent Examiner  
17 March 2006



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